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(71) Applicant (for all designated States except US):
BLUEPRINT INNOVATION LIMITED [GB/GB];
F Mill Annex, Dean Clough, Halifax, West Yorkshire HX3
5AX (GB).

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(72) Inventor; and

(75) Inventor/Applicant (for US only): **KAROL, Mihael, Jozef** [GB/GB]; F Mill Annex, Dean Clough, Halifax, West Yorkshire HX3 5AX (GB).

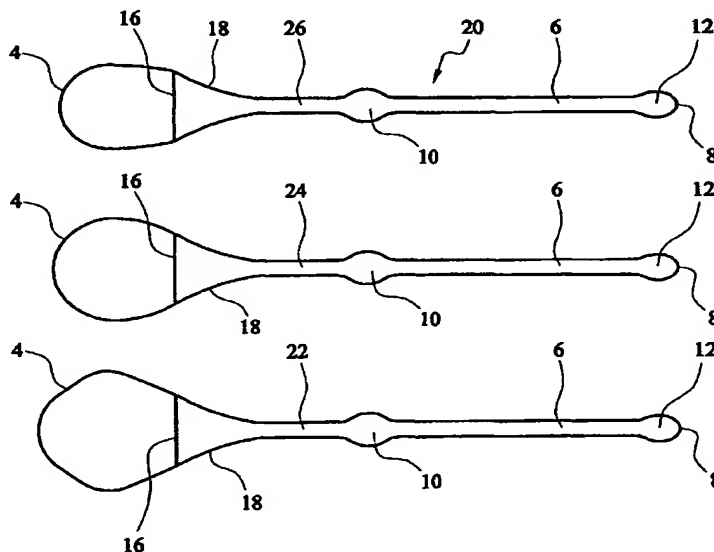
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(74) Agents: **NEILL, Alastair, William et al.**; Appleyard Lees, 15 Clare Road, Halifax HX1 2HY (GB).

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(54) Title: IMPROVEMENTS IN AND RELATING TO PELVIC FLOOR MUSCLE EXERCISERS & INDICATORS



(57) Abstract: A PFM exerciser kit (20) comprising a first PFM exerciser (22) and a second PFM exerciser (24), each PFM exerciser (22, 24) comprising a head (4) for insertion into a user's vagina and a tail (6) extending from the head (4), the first PFM exerciser (22) being heavier than the second PFM exerciser (24) and the first PFM exerciser (22) having a smaller head (4) than the second PFM exerciser (24) and/or a more gradually tapered region from the head (4) to the tail (6).

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Improvements In and Relating to Pelvic Floor Muscle
Exercisers & Indicators

Field of the Invention

5

This invention relates to pelvic floor muscle (PFM) exercisers, indicators and kits thereof. Readers will be aware that such PFM exercisers have been used in the past to cure or at least ameliorate feminine stress
10 incontinence, which is commonly attributable to the weakening of the PFMs with age, as a result of childbirth or as women approach the menopause.

Although the following description concentrates on the use
15 of devices for increasing strength of pelvic floor muscles with regard to preventing, curing or alleviating stress incontinence, it is to be mentioned that the devices hereinafter described may equally be used to test or improve the strength of pelvic floor muscles for other
20 reasons. Indeed, as has been proposed in the past, PFM exercisers can provide a valuable means of assessing the strength of PFMs as women have heretofore been generally unable to provide suitable information, often being unaware of their existence. Accordingly, the invention is
25 not to be considered limited to its particular application in the field of curing, alleviating or preventing stress incontinence, although it is this application to which the invention is ideally suited.

30

Background to the Invention

PFM exercisers and their use in preventing or at least reducing stress incontinence are both well known and
5 adequately described in the prior art.

For instance, GB-A-2058571 describes a device for exercising the perineal muscles which comprises a shaft having a tapered portion with an enlarged spherical end
10 for insertion into the vagina and includes provision for suspending various different weights from the alternate end of the shaft.

US-A-4241912 describes an isometric vaginal exercise
15 device comprising a rounded shaft having a flange at one end thereof. The shaft has a concave portion adjacent the flange, wherein the diameter of the concave portion decreases to a minimum value and then increases to a maximum value with increasing distance from the flange.
20 The concave portion allows gripping of the device by perivaginal muscles of the user. The flange is oval to permit accommodation between the legs of the user. A handle is attached to the flange end of the device.

25 EP-A-0198641 describes a set of parts for testing and/or strengthening the PFMs of wearers wherein the set comprises a number of substantially identically shaped and sized devices all adapted for insertion into the vagina beyond the PFMs so that the PFMs are automatically caused
30 to contract in an attempt to prevent the device from falling from the vagina. It is the nature of such muscles to automatically contract which can be used to strengthen same beneficially to aid or cure incontinence, as

substantially the same muscle set can be used to control or prevent the flow of urine from the bladder. This patent further describes that within the set of devices, each device is of a different weight so that the PFMs can
5 be strengthened progressively by using progressively heavier weights, each device having a lower conical portion which is in use supported by the PFMs and an upper rounded tip. The patent also mentions that the devices may be formed from a combination of materials such as for
10 example a plastic such as polymethylmethacrylate or nylon and a metal such as brass or steel provided with a suitable physiologically acceptable coating, such as may be deposited by chromium plating.

15 This device is useful as far as satisfactorily determining the heaviest weight supportable by the PFMs of a wearer is concerned, but the devices are not generally intended for domestic use nor for use in the treatment of stress incontinence. In the form described in the patent, the
20 above devices would meet with significant resistance from and limited market acceptance by the female public on account of the clinical nature of each of the devices and the lack of facility for changing the particular weight of one of the devices.

25

EP-A-392854 describes a PFM exerciser consisting of a casing having two parts which can be sealingly connected together to define a cavity in which one or more differently shaped weights can be provided to increase or
30 decrease the overall weight of the PFM exerciser as required. Moreover, the patent mentions that the device is less expensive than existing products such as those described above because only a single device is provided for

insertion, and furthermore only the casing need be of a physiologically acceptable material. In this manner, although the casings can of course be sterilised and re-used. Also, an appropriate set of weights can also be
5 provided depending on the extent to which the PFM are required to be strengthened.

Although the above device is useful and has been widely accepted in the market place, it is unnecessarily fiddly
10 to configure as both the casing and the weights tend to be small and may therefore pose difficulties as far as assembly is concerned for less dexterous people.

There is also some suggestion of multi-part PFM exercisers
15 coming apart or breaking in a woman's vagina.

A user can often find it difficult to locate and contract her PFMs. PFM exercisers can be inserted past the PFMs so it does little good. Further, even when correctly
20 inserted many women are not consciously aware of their PFMs and how to work them.

The design of PFM exercisers is in general dictated by the following important factors. Firstly the device must be
25 of a suitable shape and size for insertion into the vagina. This effectively limits the maximum diameter and its shape which is best described as being conical at one end, cylindrical through the middle and having a hemispherical other end. Secondly, the weight of the
30 exerciser must be capable of being altered to suit particular conditions or to provide more or less strenuous exercise of the PFMs.

A further design criteria of PFM exercisers which has not been as intensively assessed as those mentioned above is the physiological aspect of the device. It will be appreciated that there is resistance among women to use a PFM exerciser which although fully sterilised, has been prior used. Additionally, the types of material used in the past for such plastics have typically been plastics which although capable of being sterilised safely are hard and inflexible and thus aesthetically unappealing.

10

Users are often also reluctant to use exercisers that require repeated cleaning for fear of infection and because of the time consuming nature of such a task.

15 It is an aim of the preferred embodiments of this invention to provide an improved PFM exerciser.

Summary of the Invention

20 According to the present invention in a first aspect, there is provided a PFM exerciser kit comprising a first PFM exerciser and a second PFM exerciser, each PFM exerciser comprising a head for insertion into a user's vagina and a tail extending from the head, the first PFM exerciser being heavier than the second PFM exerciser and the first PFM exerciser having a smaller head than the second PFM exerciser and/or a more gradually tapered region from the head to the tail.

30 Suitably, a PFM exerciser kit according to claim 1, in which the kit comprises a third PFM exerciser, which third PFM exerciser has a head for insertion into a user's vagina and a tail extending from the head, and which is

heavier than the first PFM exerciser and has a smaller head than the first PFM exerciser and/or a more gradually tapered region from the head to the tail.

- 5 Suitably, the different exerciser weights are differentiated by different visual markings.

Suitably, between the head and the distal end of each tail there is provided a stop indicator for indicating to a
10 user the amount of insertion of the exerciser required.

Suitably, the stop indicator comprises a change in the diameter of each tail.

- 15 Suitably, each stop indicator comprises a bulge in the tail.

Suitably, each stop indicator is annular about the tail.

- 20 According to the present invention in a second aspect, there is provided a kit comprising a PFM exerciser and a physiologically acceptable sheath in which the PFM exerciser can be inserted for insertion into a user's vagina.

25

Suitably, the sheath is provided in an infection resistant packaging.

Suitably, the sheath comprises a condom.

30

According to the present invention in a third aspect, there is provided a PFM exerciser comprising a head for insertion into a user's vagina and a tail extending from

the head, the tail being formed from at least in part from a flexible material, and means for adjusting the angle of the tail for providing a self-supporting bend in the tail of the PFM exerciser.

5

Suitably, a tail angle adjuster comprises a jig into which the tail is inserted.

Suitably, the jig is a curved receptacle for the tail.

10

Suitably, the jig is generally U-shaped in cross-section.

Suitably, a flexible shape-retaining material can be provided at a bend region of the tail.

15

Suitably, the material is embedded in the tail.

Suitably, the tail is substantially self supporting.

20

Suitably, the PFM exerciser comprises a rubber or plastics physiologically acceptable outer layer.

25

Suitably, a plurality of weights are distributed about the head or entire exerciser.

30

According to the present invention in a fourth aspect, there is provided a method of use of a PFM exerciser the method comprising the steps of arranging a physiologically acceptable sheath at least partly about a PFM exerciser

and inserting the sheath covered PFM exerciser into a user's vagina.

Suitably, the PFM exerciser and sheath are a kit according
5 to the second aspect of the present invention.

Suitably, the sheath is discarded after use.

Suitably, the method comprises the steps of using the tail
10 angle adjusting means to adjust the tail angle and inserting the PFM indicator into a user's vagina.

In such a configuration a user can use the PFM exerciser to locate their pelvic floor muscles (PFMs). With the
15 tail in the straight configuration generally it is difficult for a user to see the tail so when they flex their pelvic floor muscles and therefore move the tail it is difficult to tell whether such movement has occurred. However with the tail in a bent configuration the tail can
20 be positioned such a way that a user can see the tail moving when their PFMs are exercised.

It will be appreciated that the various aspects of the present invention can be combined together.

25

Brief Description of the Drawings

The present invention will now be described, by way of example only, with reference to the drawings that follow;
30 in which:

Figure 1 is a plan view of a PFM exerciser according to an embodiment of the present invention.

Figure 2 is a plan view of a PFM exerciser kit according to an embodiment of the present invention.

- 5 Figure 3 is a plan view of a PFM exerciser kit according to another embodiment of the present invention.

Figure 4 is a schematic perspective illustration of a tail adjuster for use with a PFM exerciser.

10

Figure 5 is a side view of a PFM exerciser used in a PFM indicator configuration.

- 15 Figure 6 is a schematic illustration of a PFM exerciser according to a yet further embodiment of the present invention.

Description of the Preferred Embodiments

- 20 Referring to Figure 1 of the drawings that follow, there is shown a PFM exerciser 2 comprising a head 4 and a tail 6. The exerciser 2 is circular symmetrical about its longitudinal axis.

- 25 The head 4 is generally conically shaped and is suitable for insertion into a user's vagina. The tail 6 extends from the head 4 to a distal end 8. Intermediate the head 4 and distal end 8 is a stop indicator 10 comprising an annular bulge in the tail. This stop indicator bulge 10
30 changes the diameter of the tail in such a way that it can be felt by a user during insertion. A further bulge 12 is provided at the distal end 8. The bulge 12 can be useful for withdrawing the PFM exerciser 2, especially if the

tail 6 has been lubricated; the bulge 12 provides purchase for a user to grip the PFM exerciser 2.

The PFM exerciser 2 is formed by injection moulding a
5 SANTOPRENE (Trade Mark) thermoplastic rubber material to encapsulate a weight (indicated by dashed lines 14) therein. SANTOPRENE from 35 Shore A to 40 Shore D is preferred as a physiologically acceptable material that users find satisfactory from a tactile perspective. This
10 ensures the tail is substantially self-supporting. A degree of bend in the tail is permissible. This manufacturing process creates a line 16 that provides a convenient delineation between head 4 and tail 6. Strictly there is no absolute distinction between the two.

15

It is noted that there is a narrowing tapered section 18 graduating head 4 into tail 6.

In use the head 4 of PFM exerciser 2 is manually inserted
20 into the user's vagina until the user feels the stop indicator 10 indicating that the exerciser 2 has been inserted sufficiently into the user's vagina. The act of holding the exerciser in the user's vagina exercises the PFMs.

25

In practice it has been found that users vary greatly in their ability to hold a given exerciser in position. Further, as a user progresses with the exerciser the improvement they gain diminishes because their improved
30 PFMs are not being worked as hard with an initial exerciser. In the prior art this has been addressed by providing means for adjusting the weight of a single PFM exerciser, usually by the insertion therein of weights of

varying masses into an exerciser capable of disassembly and re-assembly. However, it is believed that on occasion such exercisers, especially if not done up properly, can become disassembled in use leading to difficulties for the user.

Accordingly, with reference to Figure 2 of the drawings that follow there is shown a PFM exerciser kit 20 comprising a first PFM exerciser 22, a second PFM exerciser 24 and a third PFM exerciser 26. Each PFM exerciser 22-26 is similar to PFM exerciser 2 of Figure 1 (similar reference numerals are used for like parts) except for variations in the shape of the head 4 and mass of the exerciser (governed primarily by mass 14 (not shown in Figure 2)).

Thus in Figure 2, first exerciser 22 has the largest head 4 and lowest mass (compared with second and third exercisers 24, 26, respectively). Second exerciser 24 has a head 4 size and mass intermediate first and third exercisers 22, 26, respectively and third exerciser 26 has a smaller head 4 and higher mass than first and second exercisers 22, 24, respectively.

For a user, first exerciser 22 is the easiest to hold in place due to the larger head 4 and lower weight. Second exerciser 24 and third exerciser 26 become progressively harder to hold in place as their head sizes diminish and weight increases. Thus, a user can work her way through the PFM kit using progressively harder to hold exercisers 22, then 24 and then 26. As the weight of the PFM exerciser increases in the kit, so the size of the head 4

decreases. This can be done without disassembly/re-assembly of the exerciser being required.

Although the kits shown include three exercisers, it will
5 be appreciated that any number of exercisers from 2
upwards can provide benefits. However three or four
exercisers in a kit is thought to be preferable for
providing a suitable range of exercisers for the majority
of users. The different weights can be differentiated by
10 visual markings, such as by being different colours eg
darker colours being heavier weights.

Referring to Figure 3 of the drawings that follow, there
is shown a PFM exerciser kit 30 comprising a first PFM
15 exerciser 32, a second PFM exerciser 34 and third PFM
exerciser 36. Each PFM exerciser 32, 34, 36 is similar to
that shown in Figure 1, except for variations in the shape
of the head 4, the taper 18 and the weight of the
respective exerciser, and similar reference numerals are
20 used for like parts.

Use of the kit 30 shown in Figure 3 is substantially
similar to that shown in Figure 2. However, the
difference in ease of holding for a user between the
25 exercisers 32, 34, 36 is exacerbated by their different
narrowing tapers 18 from head 4 to tail 6. First
exerciser 32 (the lightest) has an almost stepped taper 18
making it the easiest to hold. Second exerciser 34 has a
more gradual narrowing taper 18 making it harder to hold
30 than first exerciser 32. Third exerciser (the heaviest)
36 has a long gradual taper 18 making it harder to hold
than exercisers 32 and 34.

Thus the difficulty of holding can be controlled through heavier exercisers by smaller heads and/or a more gradually tapered tail.

- 5 Another difficulty users have experienced with PFM exercisers is the problem of locating and being able to flex or work their PFMs. A woman is often not consciously aware of flexing of her PFMs.
- 10 Referring to Figure 4 of the drawings that follow, there is shown a PFM indicator tail angle adjuster 40 which is a curved jig, generally U-shaped in cross-section, but so as to receive more than half of the perimeter of the tail jig. Thus tail angle adjuster 40 provides a channel 42
- 15 into which the tail is inserted. The tail angle adjuster 40 is a polypropylene moulding.

Referring to Figure 5 of the drawings that follow there is shown a PFM indicator 50 that can also be used as a PFM

20 exerciser. The PFM indicator 50 is substantially the same as the PFM exerciser 2 shown in Figure 1.

The PFM indicator 50 has had its tail 6 inserted through into channel 42 of tail angle adjuster 40 to create the

25 approximate 90° angle in the tail 6. The tail angle adjuster 40 is applied between stop indicator 10 and the distal end 8. The SANTOPRENE (trade mark) material of the tail 6 is substantially self supporting so with the tail angle adjuster 40 attached, the PFM indicator 50 adopts

30 substantially the configuration shown in Figure 5.

For use as a PFM indicator, the device is inserted into the user's vagina until the stop indicator 10 is reached.

The stop indicator 10 thus can serve a double purpose of avoiding the tail angle adjuster 40 contracting a user's vaginal area. When the stop indicator 10 is felt the end 8 of the PFM indicator can be seen by a user because of the angle at which the tail 6 is held. A user then attempts various muscle contractions until the end 8 of tail 6 is seen to twitch or move, a sign of PFM movement. The user can then recognise the muscle flexing/contractions required for PFM exercises ie to hold in the various PFM exercisers described herein.

An alternative tail angle adjuster can be provided by a flexible shape retaining strip, typically a metal strip in a bending region of the tail 6. Such a strip can be embedded in the tail 6 during the injection moulding manufacturing process. A strip 52 is shown diagrammatically in Figure 6 (see below) for ease of reference.

Referring to Figure 6 of the drawings that follow, there is shown a PFM exerciser 60 substantially similar to PFM exerciser 2 of Figure 1 (similar reference numerals are used for like parts). Additionally in Figure 6 there is shown a physiologically acceptable sheath 62, such as a condom into which at least the head 4 of PFM exerciser 60 is inserted for subsequent insertion into a user's vagina. Thus the sheath 62 protects the PFM exerciser 60 from contact with the user's vagina. After use the sheath 62 can be discarded and the PFM exerciser 60 re-used without time-consuming cleaning. It will be appreciated that the sheath 62 can be used with PFM indicators as well. The sheath 62 can be provided in a foil, plastics or other infection resistant packaging.

The reader's attention is directed to all papers and documents which are filed concurrently with or previous to this specification in connection with this application and
5 which are open to public inspection with this specification, and the contents of all such papers and documents are incorporated herein by reference.

All of the features disclosed in this specification
10 (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive.

15 Each feature disclosed in this specification (including any accompanying claims, abstract and drawings), may be replaced by alternative features serving the same, equivalent or similar purpose, unless expressly stated
20 otherwise. Thus, unless expressly stated otherwise, each feature disclosed is one example only of a generic series of equivalent or similar features.

The invention is not restricted to the details of the
25 foregoing embodiment(s). The invention extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any
30 method or process so disclosed.

CLAIMS

1. A PFM exerciser kit comprising a first PFM exerciser and a second PFM exerciser, each PFM exerciser comprising a head for insertion into a user's vagina and a tail extending from the head, the first PFM exerciser being heavier than the second PFM exerciser and the first PFM exerciser having a smaller head than the second PFM exerciser and/or a more gradually tapered region from the head to the tail.
2. A PFM exerciser kit according to claim 1, in which the kit comprises a third PFM exerciser, which third PFM exerciser has a head for insertion into a user's vagina and a tail extending from the head, and which is heavier than the first PFM exerciser and has a smaller head than the first PFM exerciser and/or a more gradually tapered region from the head to the tail.
3. A PFM exerciser kit according to claim 1 or claim 2, in which the different exerciser weights are differentiated by different visual markings.
4. A PFM exerciser kit according to any preceding claim, in which between the head and the distal end of each tail there is provided a stop indicator for indicating to a user the amount of insertion of the exerciser required.
5. A PFM exerciser according to claim 4, in which the stop indicator comprises a change in the diameter of each tail.

6. A PFM exerciser according to claim 5, in which each stop indicator comprises a bulge in the tail.
- 5 7. A PFM exerciser according to claim 5 or claim 6, in which each stop indicator is annular about the tail.
8. A kit comprising a PFM exerciser and a physiologically acceptable sheath in which the PFM
10 exerciser can be inserted for insertion into a user's vagina.
9. A kit comprising a PFM exerciser according to claim 8, in which the sheath is provided in an infection
15 resistant packaging.
10. A kit comprising a PFM exerciser according to claim 8 or claim 9, in which the sheath comprises a condom.
- 20 11. A PFM exerciser comprising a head for insertion into a user's vagina and a tail extending from the head, the tail being formed from at least in part from a flexible material, and means for adjusting the angle of the tail for providing a self-supporting bend in
25 the tail of the PFM exerciser.
12. A PFM exerciser according to claim 11, in which a tail angle adjuster comprises a jig into which the tail is inserted.
- 30 13. A PFM exerciser according to claim 12, in which the jig is a curved receptacle for the tail.

14. A PFM exerciser according to claim 12 or claim 13, in which the jig is generally U-shaped in cross-section.
15. A PFM exerciser according to claim 11, in which a flexible shape-retaining material can be provided at a bend region of the tail.
16. A PFM exerciser according to claim 15, in which the material is embedded in the tail.
17. A PFM exerciser according to any one of claims 11 to 16, in which the tail is substantially self supporting.
18. A PFM exerciser according to claim 17, in which the tail is flexible along its entire length.
19. A PFM exerciser according to any preceding claim, in which the PFM exerciser comprises a rubber or plastics physiologically acceptable outer layer.
20. A PFM exerciser according to claim 19, in which a weight is embedded inside the PFM exerciser.
21. A PFM exerciser according to claim 20, in which a plurality of weights are distributed about the head or entire exerciser.
22. A method of use of a PFM exerciser the method comprising the steps of arranging a physiologically acceptable sheath at least partly about a PFM exerciser and inserting the sheath covered PFM exerciser into a user's vagina.

23. A method of use of a PFM exerciser according to claim 22, in which the PFM exerciser and sheath are a kit according to any one of claims 6 to 10.

5

24. A method of use of a PFM exerciser according to claim 22 or claim 23, in which the sheath is discarded after use.

10 25. A method of use of a PFM exerciser according to any one of claims 11 to 21, the method comprising the steps of using the tail angle adjusting means to adjust the tail angle and inserting the PFM indicator into a user's vagina.

15

26. A PFM exerciser substantially as described herein, with reference to and as shown in the accompanying drawings.

20 27. A PFM exerciser bit substantially as described herein, with reference to and as shown in the accompanying drawings.

25 28. A kit substantially as described herein, with reference to and as shown in the accompanying drawings.

30 29. A PFM indicator substantially as described herein, with reference to and as shown in the accompanying drawings.

30. A method of use of a PFM exerciser substantially as described herein.

CLAIMS

1. A PFM exerciser kit comprising a first PFM exerciser and a second PFM exerciser, each PFM exerciser comprising a head for insertion into a user's vagina and a tail
5 extending from the head, the first PFM exerciser being heavier than the second PFM exerciser and the first PFM exerciser having a smaller head than the second PFM exerciser and/or a more gradually tapered region from the head to the tail.
2. A PFM exerciser kit according to claim 1, in which the kit comprises a third PFM
10 exerciser, which third PFM exerciser has a head for insertion into a user's vagina and a tail extending from the head, and which is heavier than the first PFM exerciser and has a smaller head than the first PFM exerciser and/or a more gradually tapered region from the head to the tail.
- 15 3. A PFM exerciser kit according to claim 1 or claim 2, in which the kit comprises means for adjusting the angle of the tail in the PFM exerciser.
4. A PFM exerciser kit according to any preceding claim, in which between the head
20 and the distal end of each tail there is provided a stop indicator for indicating to a user the amount of insertion of the exerciser required.
5. A PFM exerciser according to claim 4, in which each stop indicator comprises a bulge which is annular about the tail.
- 25 6. A PFM exerciser comprising a head for insertion into a user's vagina and a tail extending from the head, the tail being formed from at least in part from a flexible material, and means for adjusting the angle of the tail for providing a self-supporting bend in the tail of the PFM exerciser.
- 30 7. A PFM exerciser according to claim 6, in which a tail angle adjuster comprises a jig into which the tail is inserted.

8. A PFM exerciser according to claim 7, in which the jig is a curved receptacle for the tail.
9. A PFM exerciser according to claim 7 or claim 8 in which the jig is generally U-shaped in cross-section.
10. A PFM exerciser according to claim 6, in which a flexible shape-retaining material can be provided at a bend region of the tail.
11. A PFM exerciser according to claim 10, in which the material is embedded in the tail.
12. A PFM exerciser according to any one of claims 6 to 11, in which the tail is substantially self supporting.
13. A PFM exerciser according to claim 12, in which the tail is flexible along its entire length.
14. A PFM exerciser according to any preceding claim in which the PFM exerciser comprises a rubber or plastics physiologically acceptable outer layer.
15. A PFM exerciser according to claim 14 in which a weight is embedded inside the PFM exerciser.

Explanation of Claim Amendments

Claim amendments

Claims 1-15 attached replace previous claims 1-30 of the PCT application as published.

New claim 3 has been introduced and previous claims 6 and 7 have been combined with previous claim 5 to form new claim 4.

Previous claims 8-10, 21 and 22-30 have been deleted and the remaining claims have been renumbered accordingly.

-1/3-

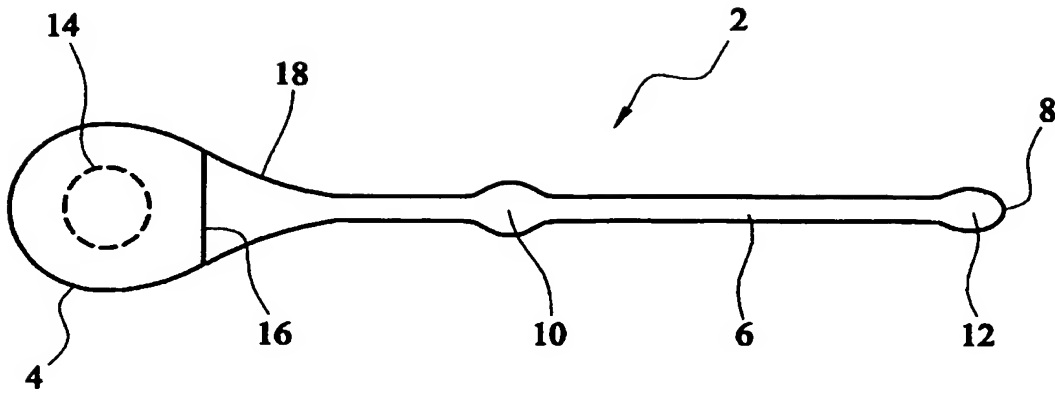


FIG. 1

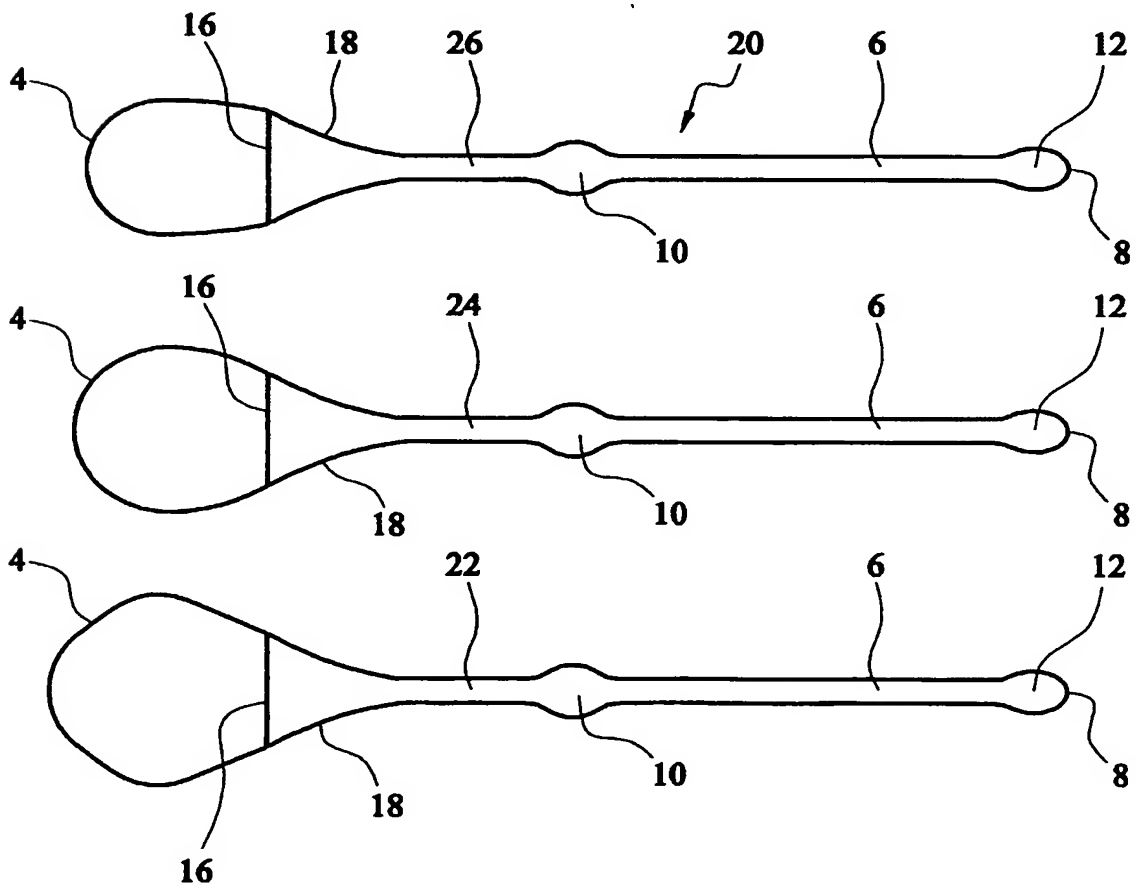


FIG. 2

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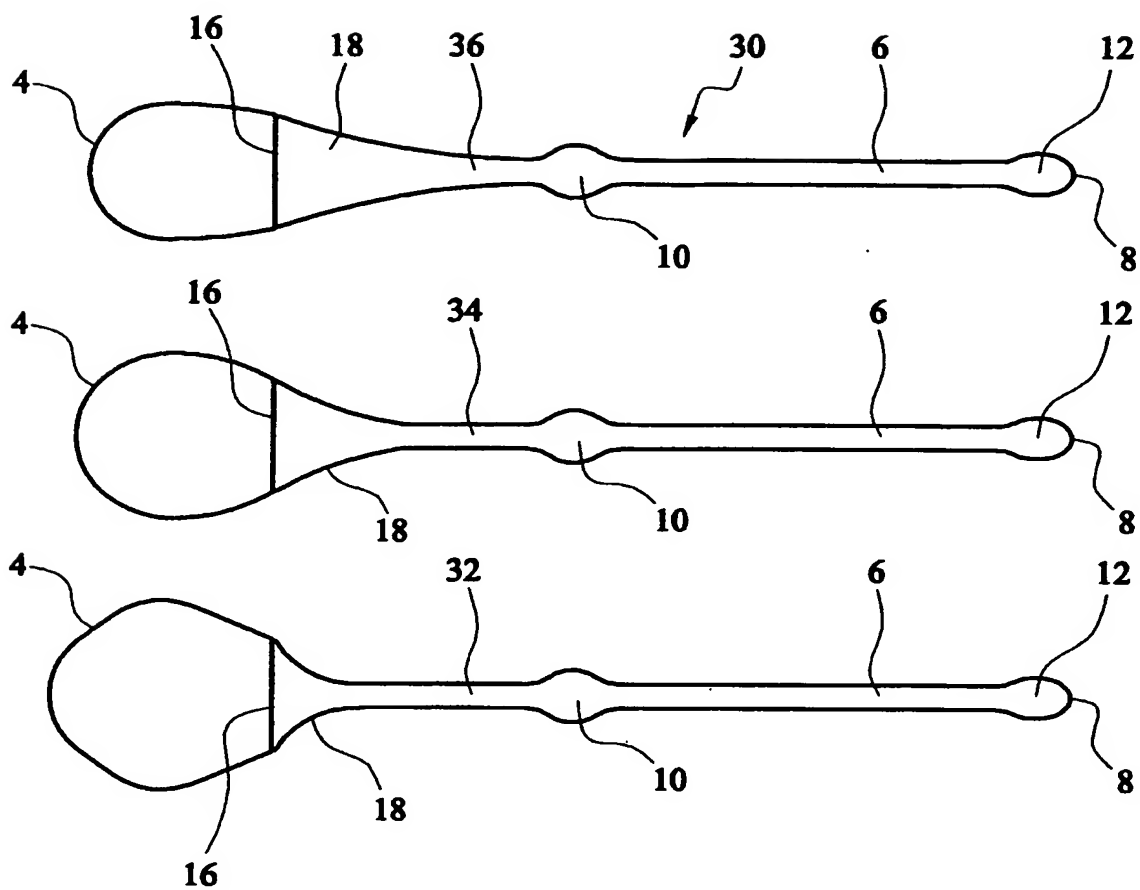


FIG. 3

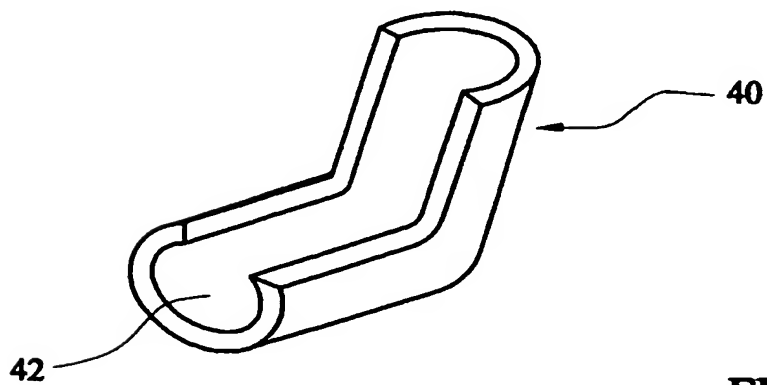


FIG. 4

-3/3-

FIG. 5

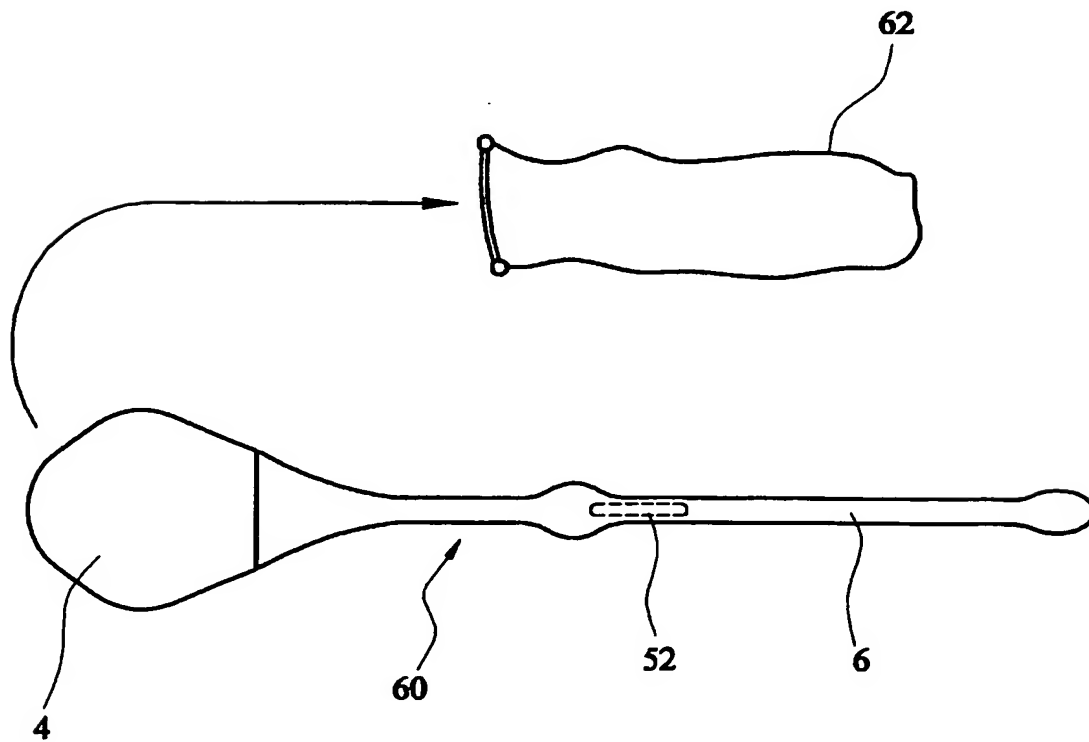
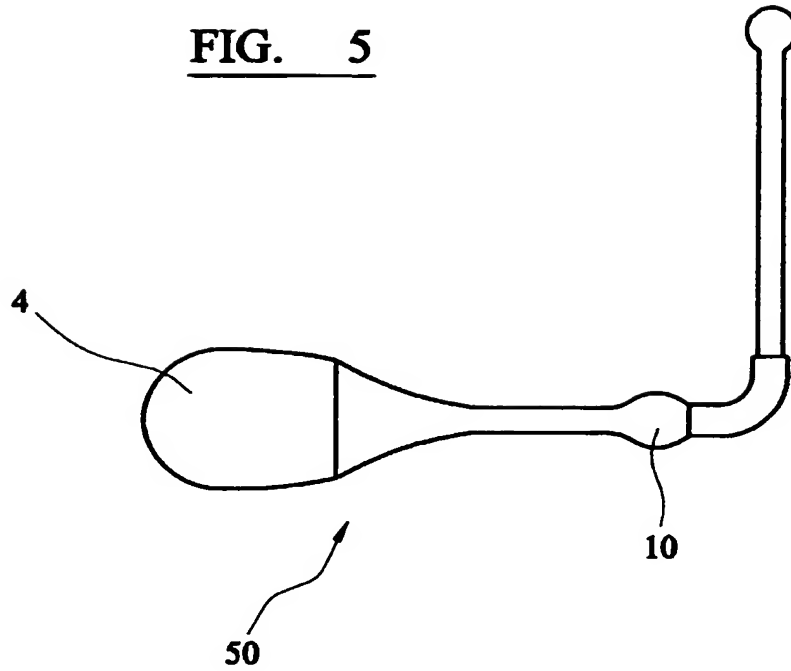


FIG. 6